ASIGA
Repeatable and precise 3D printers

EC Declaration of Conformity

Manufacturers Name:	Asiga
Manufacturers Address:	Unit 2, 19-21 Bourke Rd, Alexandria, NSW, 2015, Australia
SRN (Single Registration Number):	AU-MF-000012099
Authorized Representative Name (if applicable):	MT Promedt Consulting GmbH
Authorized Representative Address (if applicable):	Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany
Basic UDI-DI:	DentaGUIDE: 9 359215 000031 DentaTRAY: 9 359215 000093 DentaTRY: 9 359215 000345
Name of the Device (s):	DentaGUIDE, DentaTRAY, DentaTRY
Product code:	DentaGUIDE: PN / 04504 DentaTRAY: PN/ 05165 DentaTRY: PN / 05587
Classification:	Class I per Rule 5 of Annex VIII of the Medical Devices Regulations (EU 2017/745)
Intended Purpose:	The subject products are raw materials intended to be used for additive manufacture in combination with Digital Light Processing (DLP) based 3D printers that support Asiga resins to manufacture parts for Dental devices.
Notified Body name:	N/A – Class I, Self-Certified.
Notified Body Address:	N/A
Notified Body Identification number:	N/A
Conformity assessment route:	Medical Device Regulation 2017/745, Article 52(7) MDR

This declaration of conformity is issued under the sole responsibility of Asiga. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by BSI.
All supporting documentation is retained at the premises of the manufacturer.

Signature:

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Justin Elsey
Managing Director

Place and date of issue:

Alexandria, Sydney, Australia, 29/07/2022
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